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(54) Title: VACCINE

(57) Abstract: The present invention relates to IL-13 vaccines and their use in the treatment of diseases that are treatable with neutralisation of IL-13, such as COPD, asthma and atopic disorders such as hayfever, contact allergies and atopic dermatitis. The vaccines of the present invention comprise an IL-13 immunogen and an adjuvant composition which is a combination of a saponin and an immunostimulatory oligonucleotide comprising at least one unmethylated dinucleotide. The invention further relates to pharmaceutical compositions comprising such immunogens and their use in medicine and to methods for their production.





#### INTERNATIONAL SEARCH REPORT

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| According to                           | o International Patent Classification (IPC) or to both national classific  | cation and IPC   | •   |  |  |  |  |  |
|  | SEARCHED   |  |   |  |  |  |  |  |
|  | ocumentation searched (classification system followed by classification A61V C07V  | ion symbols)   |   |  |  |  |  |  |
| IPC 7                                  |  |  |   |  |  |  |  |  |
|  | tion searched other than minimum documentation to the extent that s  |  |   |  |  |  |  |  |
| Electronic d                           | ata base consulted during the International search (name of data ba  | ase and, where practical, search terms us  | ed)                                       |  |  |  |  |  |
| EPO-Internal, WPI Data, BIOSIS, EMBASE |  |  |   |  |  |  |  |  |
| C. DOCUM                               | ENTS CONSIDERED TO BE RELEVANT   |  |   |  |  |  |  |  |
| Category °                             | Citation of document, with indication, where appropriate, of the rel   | levant passages  | Relevant to claim No.                     |  |  |  |  |  |
| Υ                                      | WO 00/65058 A (M & E BIOTECH) 2 November 2000 (2000-11-02) cited in the application the whole document   |  | 1-7                                       |  |  |  |  |  |
| Υ                                      | WO 01/34645 A (THE GOVERNMENT OF UNITED STATES OF AMERICA) 17 May 2001 (2001-05-17)  | THE  | 1-7                                       |  |  |  |  |  |
|  | the whole document   |  |   |  |  |  |  |  |
| Υ                                      | WO 01/62287 A (ADVANCED BIOTHERAF<br>30 August 2001 (2001-08-30)<br>the whole document   | PY)  | 1-7                                       |  |  |  |  |  |
| Y                                      | WO 99/51643 A (THE PENN STATE RES<br>FOUNDATION) 14 October 1999 (1999<br>the whole document   |  | 1-7                                       |  |  |  |  |  |
|  | -  | ,  |   |  |  |  |  |  |
|  | <b>-</b>   | -/   | ·   |  |  |  |  |  |
| X Furth                                | ner documents are listed in the continuation of box C.   | X Patent family members are listed   | l in annex.                               |  |  |  |  |  |
| ° Special cat                          | tegories of cited documents:   | "T" later document published after the in  | tomotional filing data                    |  |  |  |  |  |
| "A" docume<br>conside<br>"E" earlier d | terrialional ning date  th the application but  theory underlying the  |  |   |  |  |  |  |  |
| filing da                              | <del></del>  | "X" document of particular relevance; the cannot be considered novel or cannot be considered nov | claimed invention                         |  |  |  |  |  |
| wnich (                                | nt which may throw doubts on priority claim(s) or<br>is cited to establish the publication date of another<br>or other special reason (as specified) | involve an inventive step when the d "Y" document of particular relevance; the   | locument is taken alone claimed invention |  |  |  |  |  |
|  | ent referring to an oral disclosure, use, exhibition or  | cannot be considered to involve an indecument is combined with one or ments, such combination being obtained.  | nore other such docu-                     |  |  |  |  |  |
| "P" docume                             | nt published prior to the international filing date but  | ments, such combination being obvious in the art.  "&" document member of the same paten   | ·   |  |  |  |  |  |
| Date of the a                          | actual completion of the international search  | Date of mailing of the international se  |   |  |  |  |  |  |
| 10                                     | D May 2004   | 18/05/2004   |   |  |  |  |  |  |
| Name and m                             | nailing address of the ISA<br>European Patent Office, P.B. 5818 Patentlaan 2   | Authorized officer   |   |  |  |  |  |  |
|  | NL - 2280 HV Rijswijk<br>Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,<br>Fax: (-31-70) 340-3046  | Moreau. J  |   |  |  |  |  |  |



Int 1al Application No PCT/GB 03/03721

| ation) DOCUMENTS CONSIDERED TO BE RELEVANT   |   |  |  |
|--|---|--|--|
| Citation of document, with indication, where appropriate, of the relevant passages                 | Relevant to claim No.   |  |  |
| WO 02/32450 A (SMITHKLINE BEECHAM<br>BIOLOGICALS) 25 April 2002 (2002-04-25)<br>the whole document | 1–7   |  |  |
| WO 02/070711 A (GLAXO GROUP LIMITED) 12 September 2002 (2002-09-12) the whole document             | 1-7   |  |  |
|  |   |  |  |
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|  | ,   |  |  |
|  | WO 02/32450 A (SMITHKLINE BEECHAM BIOLOGICALS) 25 April 2002 (2002-04-25). the whole document  WO 02/070711 A (GLAXO GROUP LIMITED) |  |  |



nformation on patent family members

Inte mail Application No PCT/GB 03/03721

| Patent document cited in search report |    | Publication date                      |          | Patent family<br>member(s) |        | Publication date         |
|--|----|---------------------------------------|----------|----------------------------|--------|--------------------------|
| WO 0065058                             | A  | 02-11-2000                            | AU       | 4100800                    |        | 10-11-2000               |
| NO 0000000                             | •• | 02 11 2000                            | CA       | 2370391                    |        | 02-11-2000               |
|  |    |                                       | CN       |                            | T      | 26-06-2002               |
|  |    |                                       | CZ       | 20013709                   | -      | 13-11-2002               |
|  |    |                                       | WO       | 0065058                    |        | 02-11-2000               |
|  |    |                                       | EE       | 200100552                  |        | 16-12-2002               |
|  |    |                                       | EP       | 1173573                    |        | 23-01-2002               |
|  |    |                                       | HR       | 20010824                   |        | 31-12-2002               |
|  |    |                                       |          | 0200958                    |        | 29-06-2002               |
|  |    |                                       | HU       |                            |        |                          |
|  |    |                                       | JP       | 20015021                   | Ţ      | 17-12-2002               |
|  |    |                                       | МО       |                            |        | 21-12-2001               |
|  |    |                                       | PL       | 351986                     |        | 14-07-2003               |
|  |    |                                       | SK       | 14832001                   |        | 04-02-2003               |
|  |    | · · · · · · · · · · · · · · · · · · · | TR<br>   | 200103046                  | 12<br> | 21-06-2002               |
| WO 0134645                             | Α  | 17-05-2001                            | AU       | 1599301                    |        | 06-06-2001               |
|  |    |                                       | CA       | 2404763                    |        | 17-05-2001               |
|  |    |                                       | EP       | 1263785                    |        | 11-12-2002               |
|  |    |                                       | WO       | 0134645                    | A2     | 17-05-2001               |
| WO 0162287                             | Α  | 30-08-2001                            | AU       | 4321901                    |        | 03-09-2001               |
|  |    |                                       | WO       | 0162287                    | A1     | 30-08-2001               |
| WO 9951643                             | Α  | 14-10-1999                            | US       | 6296843                    |        | 02-10-2001               |
|  |    |                                       | AU       | 752086                     | B2     | 05-09-2002               |
|  |    |                                       | AU       | 3377499                    | Α      | 25-10-1999               |
|  |    |                                       | CA       | 2325341                    | A1     | 14-10-1999               |
|  |    |                                       | EΡ       | 1071717                    | A1     | 31-01-2001               |
|  |    |                                       | JP       | 2002510711                 | T      | 09-04-2002               |
|  |    |                                       | US       | 2003031666                 | A1     | 13-02-2003               |
|  |    |                                       | US       | 2002159972                 | A1     | 31-10-2002               |
|  |    |                                       | WO       | 9951643                    |        | 14-10-1999               |
|  |    |                                       | US       | 6576232                    | B1     | 10-06-2003               |
|  |    |                                       | US       | 2002119120                 | A1     | 29-08-2002               |
| WO 0232450                             | Α  | 25-04-2002                            | US       | 6544518                    | B1     | 08-04-2003               |
|  |    |                                       | AU       | 4433702                    | Α      | 29-04-2002               |
|  |    |                                       | BR       | 0114786                    | Α      | 12-08-2003               |
|  |    |                                       | CA       | 2425358                    |        | 25-04-2002               |
|  |    |                                       | CN       | 1481255                    |        | 10-03-2004               |
|  |    |                                       | CZ       | 20031093                   |        | 13-08-2003               |
|  |    |                                       | WO       | 0232450                    |        | 25-04-2002               |
|  |    |                                       | ËP       | 1326638                    |        | 16-07-2003               |
|  |    |                                       | NO.      | 20031705                   |        | 14-06-2003               |
|  |    |                                       | ÜS       | 2003161834                 |        | 28-08-2003               |
| WO 02070711                            | Α  | 12-09-2002                            | BR       | 0207819                    | <br>A  | 02-03-2004               |
| MO 020/0/11                            | n  | 12 09 200Z                            | CA       | 2439628                    |        | 12-09-2002               |
|  |    |                                       | CZ       | 20032373                   |        | 14-01-2004               |
|  |    |                                       | EP       | 1368477                    |        | 10-12-2004               |
|  |    |                                       | WO       | 02070711                   |        | 12-09-2002               |
|  |    |                                       |          |                            |        | 28-01-2004               |
|  |    |                                       | HU       | 0303372                    |        | 31-10-2003               |
|  |    |                                       | NO<br>US | 20033882<br>2003194391     |        | 31-10-2003<br>16-10-2003 |
|  |    |                                       |          |                            | 44 1   |                          |